MAY 11 2000

Attachment 8

510(k) SUMMARY FOR NOUVAG AG'S MD10 Implantologie, SM12, SEM and CBM Motorsystem

Submittors's Name, Address, Telephone Number and Contact Person

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Date Prepared

February 28, 2000

Name of Devices

MD 10 Implantologie, SM12, CBM and SEM Motorsystem

Common or Usual Name

Microprocessor-Controlled Dental Drilling and Torque-controlled System

Classification Name

Dental Handpiece and Accessories (21 C.F.R. § 872.4200)

Predicate Devices

NOUVAG's Micro-Dispenser 7000/8000 (K954722) and
NOUVAG's TCM 3000/Endo (K981679)

Intended Use

Nouvag AG's („Nouvag") MD 10 Implantologie, SM12, CBM and SEM are microprocessor-controlled dental hand pieces with cooling system. The MD 10 Implantologie, SM12, CBM and SEM are intended to be used for dental implantation and microsurgery, for drilling, grinding, screwing and sawing. To reduce infections and tissue damages caused by excessive heat build-up, the device are equipped with an irrigation pump for cooling.

The models MD10 Implantologie, SM12, SEM and CBM are basically the same devices with the same motor, components and features. The difference is only given in the size of the enclosure.

Technological Characteristics

The MD10 models' primary components are (1) a console; (2) a motor; (3) a microprocessor; (4) a foot pedal; and (5) an electric cord and plug. The MD10 models are not supplied with dental drills or contra-angles or contra-angles torque wrenches, which are also called dental hand pieces. The Micromotor has a standard E-Type coupling that will fit any E-Type hand pieces and contra-angles.

The console houses the microprocessor and the motor. The buttons for setting the motor speed, contra-angle reduction ratio, motor torque are located on the operation panel of the console. The buttons that may be used to start and stop the motor and change the cut-direction of the drill, as well indication lights (LED) are also located on the front panel. The port connections for the contra-angles and the foot pedal is also on the frontside of the enclosure. The main power switch is located on the back of the console.

A lever is located on the foot pedal for starting/stopping the motor and adjusting the motor speed. One button is for start/stop the irrigation pump and one button for changing the cut direction for the drill. The MD10 models contain an audible alarm that sounds when the drill is turning in the reverse- cut direction.

The MD10 models require an AC current of 115V or 230V. An electrical cord, which is intended to be plugged into a standard electrical outlet, is attached to the back of the console.

Principles of Operation

Before the device is turned on, the operator has to set the motor speed and reduction/multiplying ratios. To select the right values, push one of the following buttons: 1:1, 1:2, 1:5, 18:1, 32:1 or 70:1. For some special contra angles and instruments preset speed and torque values are already programmed at the keys:

- key "SAW" for saws
- "DTM" for dermatome
- "MUCO" for mucotome and
- "THP" for tattooing handpiece.

The preset motor speed and irrigation pump capacity is displayed on the operation panel. The operator also has the option of setting the AS - Torque - Driver Mode. On the digital display appears the torque level. There are ten different torque levels (10, 15, 20, 25, 30, 35, 40, 45, 50 & 55 Ncm) available and the operator selects the proper torque level based on the chosen task. The built - in torque controller ensures that the drill is working constantly at the pre - selected motor torque and the pre - selected drill speed. As soon as the motor torque is equal to the pre-selected value, the motor will automatically shut-off. By utilizing this torque driver mode, the operator can avoid the risk of under - or over - tightening of screws.

The operator starts the motor with the foot pedal. There are two different foot pedals available: one foot pedal is watertight (IP68) and can be used in the operation theater (explosion protected rooms). The other foot control is class IP22 and is to be used in dry environment.

The MD10's microprocessor implements the operator's commands, displays the motor speed, and sounds an alarm if there is an electric overload or the

drill is turning in the reverse cut direction. The microprocessor has no external user interface; it simply implements the operator's commands.

Summary of the Basis for the Finding of Substantial Equivalence

The safety or effectiveness of the MD10 Implantologie, SM12, SEM and CBM is based on the safety or efficacy of the predicate device.

The MD 10, the TCM 3000/Endo and the Micro-Dispenser have the same general intended use, *i.e.*, microprocessor-controlled dental drilling, screwing, sawing and very similar indications, *i.e.*, dental implantation and oral microsurgery.

These devices have the same principles of operation. The operator of the device sets the motor speed, contra-angle reduction ratio, and the torque-levels and operates the drill by using the foot pedal controls. Although there are some minor differences in their technological characteristics, namely their contra-angle reduction-ratios and their pre-selectable torque levels. These differences do not present any new issues of safety or effectiveness. Thus, the MD 10, model Implantologie, SM12, SEM and CBM are substantially equivalent to the Micro-Dispenser 7000/8000 and the TCM 3000/Endo.

The MD 10, the TCM 3000/Endo and the Micro-Dispenser have very similar technological characteristics. More specifically, these dental drilling systems have the following features: (1) buttons on the console for setting the motor speed(s), torque levels, contra-angle reduction ratios, pump speed, (2) a foot pedal for starting/stopping the motor and adjusting the speed, (3) motor torques that are preset according to the selected contra-angle reduction, (4) safety-overload protection; (5) they require AC current, and (6) an irrigation system. All devices are microprocessor controlled. Neither device is supplied with drills or contra-angles. The MD 10 and the predicate devices TCM and Micro-Dispenser can be used with any E-type contra-angles. The MD 10, the TCM 3000/Endo and the Micro-Dispenser 7000 have one motor. The Micro-Dispenser 8000 has two motors to accommodate two contra-angles.

The technological difference between the MD 10 and the TCM 3000/Endo is their irrigation pump. The operator of the MD 10 can start the irrigation pump and adjust the pump speed. The TCM 3000/Endo has no irrigation pump at all.

Otherwise the Micro-Dispenser 7000/8000 is equipped with an irrigation pump. The cooling system is also programmable from 1 to 10 l per hour. Therefore this feature does not raise any new questions of safety or effectiveness for the device.

The second difference of the devices is that, the TCM 3000/Endo has four contra-angle reduction ratios: 1:1, 16:1, 70:1 and 20:1. The Micro-Dispenser 7000/8000 has five contra-angle reduction ratios: 1:1, 16:1, 70:1, 260:1 and 1000:1. The MD10 has six reduction/multiplying ratios (1:1, 1:2, 1:5, 18:1, 32:1 or 70:1). Therefore the MD10 and the predicate devices are operating at the most commonly used speeds for implantology and dental surgery as they accept the standard contra-angles. This difference does not raise any new questions of safety or effectiveness.

The dental drills and contra-angles are the only components of the MD10 models that may come into contact with the patient's body during dental implantation or microsurgery. As noted above, the MD10 models are not supplied with the dental drills and E-type contra-angles. Therefore, the bio-compatibility of these products need not to be demonstrated in this submission. Nevertheless, the bio-compatibility of dental drills and contra-angles has been demonstrated by their long history of safe use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

NOUVAG AG
C/O Ms. Eschbaumer
ITS Testing & Certification GmbH
Sudetenstrasse 5
D-87600 Kaufbeuren,
GERMANY

Re: K000710
Trade Name: MD 10 Implantologie, SM12, CBM, SEM
Regulatory Class: I
Product Code: EFB
Dated: February 29, 2000
Received: March 2, 2000

Dear Ms. Eschbaumer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K000710

Device Name: MD 10, SEM, CBM, SM 12

Indications For Use:

To be used in oral applications for implantology and micro-surgery for drilling, grinding, screwing and sawing with a built-in cooling system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000710